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Development of an International Prostate Cancer Outcomes Registry.

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Abstract

Objectives: To establish a Prostate Cancer Outcomes Registry-Australia and New Zealand (PCOR-ANZ) for monitoring outcomes of prostate cancer treatment and care, in a cost-effective manner.

Materials and methods: Stakeholders were recruited based on their interest, importance in achieving the monitoring and reporting of clinical practice and patient outcomes, and in amalgamation of existing registries. Each participating jurisdiction is responsible for local governance, site recruitment, data collection, and data transfer into the PCOR-ANZ. To establish each local registry, hospitals and clinicians within a jurisdiction were approached to voluntarily contribute to the registry following relevant ethical approval. Patient contact occurs following notification of prostate cancer through a hospital or pathology report, or from a cancer registry. Patient registration is based on an opt-out model. The PCOR-ANZ is a secure web-based registry adhering to ISO 27001 standards. Based on a standardised minimum data set, information on demographics, diagnosis, treatment, outcomes, and patient reported quality of life are collected.

Results: Five of nine jurisdictions have signed a Local Responsibility Agreement to contribute to the PCOR-ANZ. Each jurisdiction has commenced implementation of necessary infrastructure to support rapid rollout. PCOR-ANZ has defined a minimum data set for collection, to enable analysis of key quality indicators that will aid in assessing clinical practice and patient focused outcomes.

Conclusion: PCOR-ANZ will provide a useful resource of risk-adjusted evidence-based data to clinicians, hospitals, and decision makers on prostate cancer clinical practice.

Key words: prostate cancer, clinical registry, population health

Introduction

Prostate cancer is the most commonly diagnosed cancer among Australian males apart from non-melanoma skin cancers, affecting 1 in 7 men by age 75 (1). In 2010, 19,821 new cases, and 3224 deaths from prostate cancer were reported in Australia (1). Management options include active surveillance, watchful waiting, surgery, external beam radiotherapy, brachytherapy, hormone deprivation therapy, chemotherapy, or a combination of these. The choice of treatment is dependent on disease stage, age at diagnosis, caseload of the diagnosing hospital, quality of patient-physician relationship, preference by patients to

receive the most advanced technology, lifestyle, existing comorbidities, and distance to treatment centres (2-4).

While survival rate is high, with 10- and 15- year survival rates being 93%, and 77% respectively (5), treatment of prostate cancer is often associated with adverse effects including recurrence, functional and emotional dysfunctions, and loss of quality of life (6, 7). Long-term monitoring of these effects enables an understanding of clinical care. Population studies have shown that several factors influence patterns of treatment, care, and patient outcomes.

Differences in demographics are noted, where men in rural areas have higher mortality, PSA levels and histopathological grades, and poorer survivals, compared to men in urban areas (8). PSA testing is also lower in rural areas than metropolitan areas (9). Ethnic differences are also evident with mortality being higher in Aboriginal men compared to non-Aboriginal men (10).

Socioeconomic status, comorbidities, and patterns of care provided in urban versus rural communities and in the public versus private systems, play a role in demographic and ethnic differences. Men without medical insurance are more than twice as likely to have a longer than median diagnostic and treatment interval than those with private medical insurance (11). Access delay is evident in men who chose to have radiotherapy alone, with Queensland data showing a fourfold higher treatment interval of greater than 70 days compared to those receiving surgery (OR 4.22, 95% confidence interval 2.4-7.6) (11).

Compared to men notified from public hospitals, men notified from private hospitals with localised disease are significantly less likely to receive radical treatment (12) and have positive surgical margins following radical prostatectomy (13); even after accounting for age and stage of disease at diagnosis. While not population-based, the methods of data collection by the registry were consistent across both private and public hospitals.

Together these studies suggest a need to monitor incidence, survival, clinical practice, and patient outcomes, and to provide quality assurance programs and performance feedback systems, and thereby improve diagnosis, treatment, care, and recovery.

The annual cost for prostate cancer care in Australia in 2008-09 was estimated at $349 million; accounting for 16% of the cost of all cancer health expenditure for males and up 23% from the previous four-year period (14). There is some evidence that prostate cancer

survivors consult their GPs more times annually than age-matched non-cancer controls (15). Unrestrained, the effect of increasingly early disease diagnosis and treatment will be that the annual cost of prostate cancer management will continue to grow at an alarming pace (12).

Traditionally, cancer registries provide details on trends in cancer incidence and survival (16) but do not collect screening or treatment information, or important outcome measures such as quality of life. Clinical quality registries provide capacity to collect this information and deliver feedback to healthcare providers to implement practice changes of clinical and economic significance. Feedback is often provided in the form of compliance with quality indicators that monitor processes and outcomes of care (17). Multidisciplinary team meetings, traditionally used to discuss and positively affect patient management decisions,(18) provide an ideal structure to be used for dissemination and actioning of data from clinical quality registries.

Given our present understanding of the cost of prostate cancer care, and existing unexplained variations in treatment and outcomes, a Prostate Cancer Outcomes Registry–Australia and New Zealand (PCOR-ANZ) is being developed to provide an evidence base. This registry will provide a comprehensive data resource regarding the care and outcomes of Australian and New Zealand men with prostate cancer, thereby enabling monitoring of treatment and outcomes and fostering research into survival and improving quality of treatment and care at a national level. The aim of this paper is to describe the establishment and implementation of the PCOR-ANZ.

Materials and Methods

Objectives

In 2013, the Movember Foundation, a Men's Health Charity Organisation, funded an initiative to seek consensus on implementation of the PCOR-ANZ.

The primary aim of the PCOR-ANZ is to establish a population-based prostate cancer clinical registry to improve quality of care provided to Australian and New Zealand men diagnosed with prostate cancer. The PCOR-ANZ will identify patterns of care, variation in treatment and outcome, compliance with best practice-based guidelines, factors that predict favourable and unfavourable treatment outcomes, and provide information to patients about the risks and benefits of specific treatment options.

The PCOR-ANZ will provide opportunity to improve knowledge of prostate cancer and advance treatment by monitoring trends in incidence and survival. This will provide an infrastructure on which intervention or other studies may be established and provide capacity for clinical data and biomarker linkage studies to identify biological associations. The PCOR-ANZ aims to capture 90% national representative data on the diagnosis, treatment, and quality of life of men diagnosed with prostate cancer, over three years.

Establishment of Lead Organisations

Movember released an Expression of Interest in June 2013, to invite groups to nominate their interest in leading a prostate cancer registry in each of Australia's eight jurisdictions. It was determined that each jurisdiction would collect data and transmit a core data set to a national repository. A custodian for the national repository was sought concurrently. In 2015, New Zealand was recruited to participate.

Governance

Following appointment of a lead group in each jurisdiction, and of the national custodian, a Local Responsibility Agreement outlining the roles and responsibilities of participating jurisdictions and of the PCOR-ANZ, was developed. In brief, the Agreement is a contract between each jurisdiction and the PCOR-ANZ custodian. It stipulates that each jurisdiction be responsible for the ethical management and governance of their local registry database. Governance structures were developed in accordance with the Operating Principles and Technical Standards for Australian Clinical Quality Registries as detailed previously (19), and include guidelines on data handling, storage, and access.

The PCOR-ANZ Steering Committee, comprising key stakeholders, including nominated representatives from professional societies and representatives from each participating jurisdiction, will govern the overall management, and will review presentations by Committee members as well as requests for access to data contained in the PCOR-ANZ.

Stakeholder Engagement

Participating jurisdictions will be responsible for the recruitment of treatment sites and clinicians, including obtaining and maintaining all relevant ethics applications. In public hospitals, recruitment of clinicians involves a discussion with the Head of Unit involved in the care of men undergoing prostate cancer treatment, supported by a presentation to hospital personnel. A lead person is appointed for each site, to whom quality indicator reports will be communicated for further distribution. In private hospitals, diagnosing

clinicians sign a consent form to have their patients listed, and to allow data collectors access to their patients' medical records to collect the minimum dataset.

Participant Recruitment and Consent

This project has received ethics approval from Monash University (CF14/1693 – 2014000832) and the NSW Population and Health Services Research Ethics Committee (HREC/15/CIPHS/7). All men, above 18 years of age, who have been diagnosed or treated for prostate cancer in participating sites, are eligible to participate in the PCOR-ANZ.

The method of identifying eligible patients is dependent on the source of prostate cancer notifications. Notifications may relate for cases mandatorily reported to State-based cancer registries, or come from individual hospitals, surgical centres, or pathology providers. Eligible patients must have a diagnosis confirmed by either pathology examination or imaging, occurring from up to ten months prior to the study commencement date of the participating site. This time limitation is assigned such that patient outcomes may be recorded twelve months after commencement of treatment. Upon receipt of a notification, patient health status is verified before further contact is made.

Patient information and consent forms, explaining the registry, data collection, and option to opt-out at any time, are provided to all prospective participants. A waiver of consent enables collection of diagnostic and treatment data on men who have died before providing consent, and on men diagnosed via a transurethral resection of the prostate where their clinician has requested that no patient contact occur.

Data Collection

Working groups were responsible for defining a minimum data set and tools to assess patient-reported outcomes.

A Data Elements Working Group determined clinical variables to be collected. The group comprised of radiation oncologists, urologists, epidemiologists, and research scientists; four members being Directors of cancer registries. The group was provided with a comprehensive list of data items collected by each State/Territory cancer registry (20), and by prostate cancer-specific registries in South Australia (21), Victoria (19) and United States (22). Feasibility and utility of collecting each of the data items at a population level was considered in developing the minimum data list for collection by the PCOR-ANZ.

A Survivorship Working Group determined patient reported outcome measures to be collected. The group comprised psychologists specialising in prostate cancer quality of life assessment, prostate cancer researchers, epidemiologists, an urologist and a radiation oncologist. Following consultation with men diagnosed with prostate cancer, their carers and spouses, and healthcare professionals, Movember developed a set of Health Statements. These statements represent the optimal outcome men should expect to achieve after diagnosis and management of prostate cancer. Through discussion and systematic review of the literature, the Survivorship Working Group identified potential instruments to address the Health Statements.

Data Access and Release for Research

Researchers must complete and submit a data request form, detailing their research proposal, to the PCOR-ANZ Steering Committee for critical review. Relevant forms are available from the registry's website. Based on proposal and design, feasibility, and impact on healthcare, and following receipt of relevant ethics commitment certificates, accepted requests will receive a non-identifiable dataset including the fields specifically requested. Researchers must advise the PCOR-ANZ Steering Committee of all accepted publications to avoid duplication of studies and to minimise conflict of interest.

Results

Participating Jurisdictions

Thus far, New South Wales, Queensland, South Australia, Tasmania, and Victoria have signed an agreement to be contributors to the PCOR-ANZ. These jurisdictions account for 89% of prostate cancer cases in Australia (14). Each jurisdiction has formed a local Steering Committee for local governance as detailed previously (19), and is establishing the necessary infrastructure to support rapid rollout of site and patient recruitment, data collection, and data transfer.

Site and Patient Recruitment

Site recruitment is modelled from the strategy employed by the Victorian Prostate Cancer Registry (19) where selected representative regional, metropolitan, public, and private hospitals, with high prostate cancer notifications, are initially recruited, progressively increasing subsequent site recruitment over time. A limiting process in site recruitment in South Australia and Victoria is the necessity of obtaining ethics approval from each site, highlighting the need for a central ethics administration (23). In all other Australian States and Territories, a central ethics governing body is effectively and successfully deployed; however, each hospital is required to review governance arrangements, including resource

requirements and impact to the hospital, which can lead to significant delay in commencement of data collection.

Upon site recruitment and ethics approval, notifications of newly diagnosed prostate cancer cases are sent to the associated local registry. In Victoria and New South Wales, by law, their State cancer registry receives notifications from the diagnosing hospital. The registry then sends these notifications to the local prostate cancer registry, within three months post patient diagnosis. In other jurisdictions, the participating hospital or associated pathology clinic sends notifications directly to the local prostate cancer registry, at the time of notifying the State cancer registry. Upon receipt of notifications, patient recruitment follows through a mail out of an explanatory statement and opt-out consent (Fig 1). For patients who do not opt-out of the registry, data collection commences two weeks following mail out (19); however participants are able to opt-out at any time. An opt-out registry was chosen because, where individuals are required to actively enrol in a registry ("opt-in"), recruitment is low with resulting poor quality data which are inadequate for driving quality improvement (24). Patient recruitment for each jurisdiction is dependent on site recruitment as well as efficiency of transmission of notifications into the local registry.

Minimum Data Set and Quality Indicators

Consensus on the minimum dataset (Tier 1; Table 1) was obtained through discussion and voting. Data fields not listed or defined in the Cancer (clinical) dataset (20), were defined using existing data dictionaries (25). Data items were classified in descending order of importance as mandatory (Tier 1), additional (Tier 2), and value adding (Tier 3). Establishing a national registry necessitates a data set that allows participation of all sites. Smaller clinics and hospitals may not have the resources to collect Tier 2 and Tier 3 data elements, therefore these were classified as optional for collection. As the program develops, and through alignment with international data collection for prostate cancer clinical registries, the PCOR-ANZ core data set may be extended to include additional key clinical variables.

The Survivorship Working Group identified tools to monitor nine of twelve Health Statements (Table 2). In accord with the International Consortium for Health Outcomes Measurement (ICHOM) recommendation (26), the EPIC-26 tool was selected to assess disease-specific quality of life because it had demonstrated strong psychometric properties (27). It was recommended that the EPIC-26 survey be administered to the participant prior to treatment, where possible, and at 12 months post final active treatment (26), using either telephone, SMS, paper-based or web-based forms. The modality will be trialled across

jurisdictions to assess cost per case accrued and completeness of case ascertainment. (28). Random sampling will be used to assess survivorship issues outlined in the Health Statements, with an implementation plan to be ratified by the PCOR-ANZ Steering Committee.

In order to provide capacity for international benchmarking, a core set of quality indicators is under development. Each jurisdiction will generate quality indicator reports, distributing the reports to the lead person of participating sites. These reports will not identify individual clinicians but will enable hospitals to view the hospital performance against the indicators relative to the population mean and to other unnamed hospitals. On hospital recruitment, the hospital lead person will communicate to the registry the quality indicator report dissemination plan.

Registry Infrastructure

Two prostate cancer registries exist in Australia; one in South Australia (21) and the other in Victoria (19). Jurisdictions may choose to use either of these database templates to form their local registry database. Each jurisdiction will collect Tier 1 data elements and patient reported outcomes, and securely transfer the data electronically to the PCOR-ANZ at least biannually. Transmitted data must pass Quality Assurance and Quality Control validation checks prior to transfer. These checks identify duplications, discrepancies, outliers, and data entry errors. A random sample of cases will undergo audit, at quarterly intervals, to verify data elements and ensure consistency of approach across jurisdictions. Data transfer to the PCOR-ANZ must comply with ISO 27001 certification (29).

Discussion

According to World Health Organization GLOBOCAN estimates for 2012, Australia and New Zealand had the highest incidence of prostate cancer in the world (30). As survival rate is high, albeit burdened with adverse functional and emotional dysfunctions, management of the disease is of great community and economic interest.

Clinical registries allow ongoing monitoring and benchmarking of clinical management and treatment outcomes, and thus are considered among the most effective strategies for quality healthcare improvement (31). Monitoring disease incidence, progression, treatment outcomes, and quality of life, are key indicators for best practice guidelines and healthcare policies, to ensure the best outcomes for the patient and the community. Increasingly with active surveillance being the recommended approach to managing low risk disease, registries have already proven useful in understanding current practice. (32) Forming an

international registry strengthens the ability to draw conclusions from the data. The PCOR-ANZ provides an invaluable resource of information on clinical practice, outcomes of prostate cancer management, and means of projecting the future cancer burden. It provides real-world data, enabling identification of areas of excellence as well as areas of concern in the management of the disease.

To build a successful clinical registry, careful planning is key for identifying stakeholders, assessing feasibility, building a team, and establishing a viable governance and oversight plan (33). In each jurisdiction, differing laws on public healthcare policy, data access and release, and for obtaining primary health data, impose a challenge in setting up an international registry, and require Local Responsibility Agreements as a binding legal document with each jurisdiction.

Team players having authority, leadership qualities, collaborative networks, a vision for positive change, and capacity to motivate participation, are ideal candidates for governance and implementation of the local registry and for building a team. Well-planned strategies for enrolment and retention enable a solid representation of the target population within the registry. Factors that motivate participation include perceived relevance, importance, and scientific credibility of the registry (33).

A number of challenges still exist. An assessment on the feasibility of the registry to impact on healthcare practice and its ability to acquire data with minimum burden is required. While the PCOR-ANZ Steering Committee has endorsed the minimum dataset, it will evolve as new diagnostic techniques and treatment options become available, as the international quality indicator set is determined, and as outcome measures are further developed. Similarly, quality indicators will grow as stakeholders request reports of hospital case-load, surgical experience, health insurance status, and other factors increasingly shown to affect patient treatment and care outcomes. Quality indicators will need to be responsive to changes in evidence-based guidelines. Nevertheless, it will remain critical to define a minimum set that is achievable for collection by the majority of potential sites.

Clinical registries provide a resource of data to monitor clinical and hospital practice, patient health outcome, and population health, and have the capacity to generate data with significant implications for healthcare policies and economics. With growing interest in the establishment of clinical registries, long-term funding to support their development and maintenance requires thought. A model of shared funding by hospitals, health insurers,

government departments, philanthropists, and private organisations, may aid in the efficient and rapid growth and implementation of such crucial resources.

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Conflicts of Interest Statement

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Table 1: Tiered data elements collected by the Prostate Cancer Outcomes Registry – Australia and New Zealand

Tier 1 – mandatory (core)	Tier 2 – additional	Tier 3 – value adding
PERSON:		
Family name	Address line	Country of birth
Given name(s)	AIHW Birth-date Accuracy Estimator	Main language spoken at home
Postcode	ATSI status	
Date of birth	Individual Healthcare Identifier (IHI)	
Vital status	Medical Record Number	
Date of death	Medicare Card Number	
Cause of death		
FAMILY HISTORY		
		1st degree members diagnosed
		1st degree members diagnosed (text)
		1st degree member age at diagnosis
PROVIDER (organisation):		
	Healthcare Provider Identifier (HPI-O)	
DIAGNOSIS:		
Diagnosis date	Most valid basis of diagnosis	
	AIHW Diagnosis-date Accuracy Estimator	
ASSESSMENT AT DIAGNOSIS:		
PSA (last PSA pre-biopsy):	Symptoms	Performance status (ECOG)
Date	Imaging investigations	Region of prostate with highest Gleason score
Level (ng/mL)	Biopsy type	Gestalt pattern
Biopsy core results	Total length of tissue in cores:	Biopsy 2nd most common
Biopsy: Presence of tumour	Total linear length of cores examined-(all cores) (mm)	Higher tertiary
Biopsy histology type	Total linear length of tumour (all cores) (mm)	-PIN (high grade)
Biopsy number of core specimens	Percentage of tissue positive for tumour (derivable)	
Biopsy number of cores examined	-M sites	
Biopsy number of cores positive for tumour	-Staging scheme edition	
Gleason grade:		
Gleason primary (dominant/most prevalent)		

Gleason secondary		
Gleason highest grade		
Specified grade (for unusual histology types)		
Clinical TNM assessment		
Clinical T		
Clinical N		
-Clinical M		
-TNM-overall grouping		
-TNM text		
-Staging scheme edition		
CLINICAL MANAGEMENT (initial round):		
TREATMENT:	Intent (curative/non-curative)	
-Surgery	TRIAL:	
-Radiotherapy	-Trial entry status	
-ADT (Chemical)	-Experimental agent/protocol	
-ADT (Surgical)	-Trial name/number	
-Chemotherapy	-Entry date	
-Other systemic therapies	-Completion date	
-Other treatments		
-Watchful waiting		
-Active surveillance		
SURGERY:		
-Date	-Lymphatic/vascular invasion	Surgery institution
-Type	-Extent	-Nerve sparing
-Approach	Regional nodes:	-Pelvic lymph node dissection
Surgical pathology:	-Number examined	-Multifocal
-Histology type	-Number positive	-Prostate region (highest Gleason score)
-Gleason grade:	-Margin involvement (<3mm/3+mm)	-Location1
-Primary		-Location2
-Secondary		-Seminal vesicle invasion:
-Tertiary (if applicable)		-Occurrence (y/n)
-Extra-prostatic extension:		-Region involved (R/L/both)
-Status (no/yes)		Margin involvement (mm)
Pathological TNM assessment:		-Surgical complications:
-T		-Clavian grade
-N		-Specific
-M		-Text

-TNM grouping		-Medical complications:
-TNM text		-Occurrence
-Staging scheme edition		-Text
Surgical outcome:		
-Margin involvement:		
-Clear/involved/equivocal		
RADIOTHERAPY:		
-Radiotherapy type	--Dose (Gy)	--Radiotherapy institution
-External beam	--Fractions	
--Occurrence	--Delivery code	
--Start date		
--Completion date		
-Brachytherapy		
--Occurrence	Dose (Gy)	
--Start date (first implant)	Dose rate (HDR/LDR)	
--Completion date (last implant)	Fractions	
ANDROGEN DEPRIVATION THERAPY:		
-Agent start date	-ADT Delivery	If neoadjuvant/adjuvant:
-Agent stop date		-Agent 1
-Surgical ADT date		-Agent 2
		-Agent 3
		If palliative:
		-Agent 1
		-Agent 2
		-Agent 3
		-Surgical
		-Agent start date
		-Delivery
		-Agent stop date
		-Surgical ADT date
CHEMOTHERAPY:		
-Start date	-Agent/protocol 1	
-End date	-Agent/protocol 2	
-Text field	-Agent/protocol 3	
	-Agent/protocol 4	
	-Agent/protocol 5	
OTHER SYSTEMIC THERAPIES (e.g., hormone therapy):		
-Start date	-Agent/protocol 1	

-End date	-Agent/protocol 2	
-Text field	-Agent/protocol 3	
	-Agent/protocol 4	
	-Agent/protocol 5	
OTHER TREATMENTS:		
-Text field		
RELAPSE/RECURRENCE:		
-Clinical relapse:		
--Occurrence	--Region	--Distant recurrence site
--Date of initial event	-Castrate resistance-date of initial event	
-Biochemical relapse:	Treatment of relapse/recurrence	
--Occurrence	Treatment type	
--Date of initial event	Text field	
-Castrate resistance:		
FOLLOW-UP		
Last contact date	PSA LOG (including sentinel follow-ups)	
Last known cancer status	PSA during treatment date	
	PSA during treatment level (ug/L)	
	PSA at end of treatment date	
	PSA at end of treatment level (ug/L)	
	PSA at follow-up 1 date (e.g., at 12 months)	
	PSA at follow-up 1 level (ug/L)	
	PSA at follow-up 2 date (e.g. at 24 months)	
	PSA at follow-up 2 level (ug/L)	
	PSA at follow-up 3 date (e.g., at 36 months)	
	PSA at follow-up 3 level (ug/L)	
	PSA at follow-up 4 date (e.g., at 48 months)	
	PSA at follow-up 4 level (ug/L)	
	PSA at follow-up 5 date (e.g., at 60 months)	
	PSA at follow-up 5 level (ug/L)	

Table 2: Movember health statements

MEN LIVING WITH PROSTATE CANCER CAN SAY:	TOOL PROPOSED TO ASSESS PERFORMANCE AGAINST HEALTH STATEMENT
A. My information, treatment, care, and support needs have been met	
• I had access to well-coordinated advice and care	Nil available
• I made a well-informed treatment decision that I do not regret	Decision Regret Scale [39]
• I had access to the treatment of my choice	Nil available
• The practical support needs of my partner, family, carers and I have been met	Supportive Care Needs Survey [40]
B. I am physically well	
• I have fully recovered from any urinary dysfunction that I had	Extended Prostate Cancer Index Composite-26 (EPIC-26 [41]
• My partner and I are satisfied with the level of sexual function I have	Extended Prostate Cancer Index Composite-26 (EPIC-26 [41]
• I have fully recovered from any bowel dysfunction that I had	Extended Prostate Cancer Index Composite-26 (EPIC-26 [41]
• My partner, family, carers and I are effectively managing any pain, fatigue, nausea and other symptoms experienced	Extended Prostate Cancer Index Composite-26 (EPIC-26 [41] ***or*** EORTC QLQ-C30 [42] ***or*** SF-12v2 [43]
C. I am mentally well	
• My partner, family, carers and I know what to expect during and after treatment, including when and where to seek help if specific issues arise	Nil available
• My partner, family, carers and I are able to live a meaningful life in the community of my choice	Warwick-Edinburgh Mental Well-being Scale [44]
• My partner, family carers and I have accepted and are prepared for the possible consequences and outcomes of my cancer and my treatment(s)	Distress Thermometer [45]
• My partner, family, carers and I are not depressed or anxious	MAX-PC[46] ***or*** HADS[47] ***or*** K10[48]

*The Distress Thermometer is used to screen for global psychological distress and this was felt to be covered in part in this question

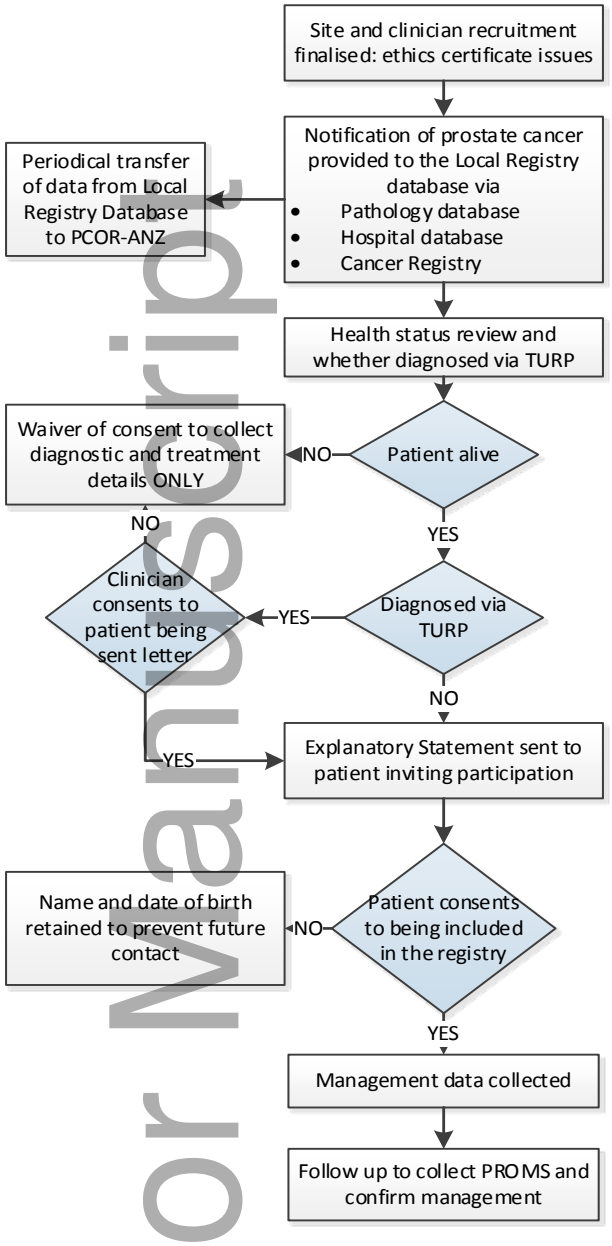

Figure 1: Patient recruitment flow chart.